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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,382	04/08/2004	Matthew Peterson	TPIP039	8458

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TRANSFORM PHARMACEUTICALS, INC.
29 HARTWELL AVENUE
LEXINGTON, MA 02421

EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,382	PETERSON ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of group I, claims 1-9 in the reply filed on Dec. 21, 2004 is acknowledged.

Applicant's intention of canceling claims 10-21 should be made in the record. Claims 10-21 remain withdrawn until applicants' cancellation.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augart et al. Us 6,054,482 (cited on 1449) in view of Berge et al. J. Phar. Sciences.

Determination of the scope and content of the prior art (MPEP §2141.01)

Augart et al. '482 disclosed purified, crystallized hydrochloride salt of gabapentin (see col. 6, example 1).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Augart et al. '482 and the instant claims is that other pharmaceutically acceptable addition salts were not described. Berger et al. disclosed advantage of useful pharmaceutically acceptable addition salts and a list of FDA approved commercially

marketed addition salts were explicitly named on page 2 and among which hydrochloride, tart rate, male ate and edisylate (also known as 1,2-ethanedisulfonate) were analogously described.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the Augart et al. '482 reference and the FDA guidelines would be motivated to prepare the instantly claimed specific salts of the claims since they were generically approved by FDA to be desirable for commercial market. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Augart et al. '482 in view of Berge et al. further in view of US pharmacopia #23 and Rouhi Chem. Eng. News.

The finding of claims 1-6 prima facie obvious over the primary references Augart et al. '482 in view of Berge as delineated supra is hereby incorporated by reference.

The dependent claims 7-9 included limitation of X-ray diffraction peaks. The physical property of a compound is the innate nature of that product. Therefore, the claims with the X-

ray peaks are essential duplicates since a product can not be separated from its innate nature. The rejection supra therefore is applicable and incorporated by reference to claims 7-9.

Further, it is recognized in the art that "many compounds are capable of crystallizing in more than one type of crystal lattice" (p.1843 US pharmacopia, right column) therefore, even if the X-ray peaks are different forms of products, it is prima facie obvious in view of US pharmacopia that mere existence of multiple forms of crystals is prima facie obvious.

It is well recognized in the art that different pharmaceutically acceptable addition salts i.e. "various salts of the same compound often behave quite differently....bioavailability"(see Berge (.2 left column) and polymorphs have different bioavailability and physical properties (see Rouhi, p. 33 left column). Therefore, mere existence of *difference* between the instantly claimed salt from the known salt in property, form and physical data is *expected.* The specification disclosed none of the salts as claimed to have "unexpected" properties over the ordinary pharmaceutically acceptable addition salts. Please note that polymorph of a known compound can be patented when it has unexpected properties (see Rouhi p. 34 left column).

Therefore, one having ordinary skill in the art in possession of the above references would find the instant claims 1-9 prima facie obvious **because** the instant claims are drawn to more specific salts and their physical properties. One guided by the commercial marketable pharmaceutical salts selection would be motivated to prepare any alternatives named by the FDA guideline with the expectation that each salt would have different physical property and such salt, if forms crystals, some would form multiple forms with different physical properties. In absence of unexpected results, there is nothing unobvious in choosing some among many and the innate nature of the chosen some is expected i.e. inherent for the chosen product.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
April 25, 2005

Celia Chang
Primary Examiner
Art Unit 1625